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United States Patent [19]

Lichtenstein et al.

[11] Patent Number: 5,593,441

[45] Date of Patent: Jan. 14, 1997

[54] METHOD FOR LIMITING THE INCIDENCE OF POSTOPERATIVE ADHESIONS

[75] Inventors: **Irving L. Lichtenstein**, Marina Del Rey, Calif.; **Carl R. Turnquist**, Concord, Mass.; **Parviz K. Amid**, Calabasas, Calif.

[73] Assignee: **C. R. Bard, Inc.**, Murray Hill, N.J.

[21] Appl. No.: **472,261**

[22] Filed: **Jun. 7, 1995**

Related U.S. Application Data

[63] Continuation of Ser. No. 376,735, Jan. 23, 1995, abandoned, which is a continuation of Ser. No. 846,131, Mar. 4, 1992, abandoned.

[51] **Int. Cl.**[6] **A61F 2/02**

[52] **U.S. Cl.** **623/11**; 600/37; 623/66; 606/151; 606/213

[58] **Field of Search** 623/11, 16, 66; 600/151, 213, 215, 37

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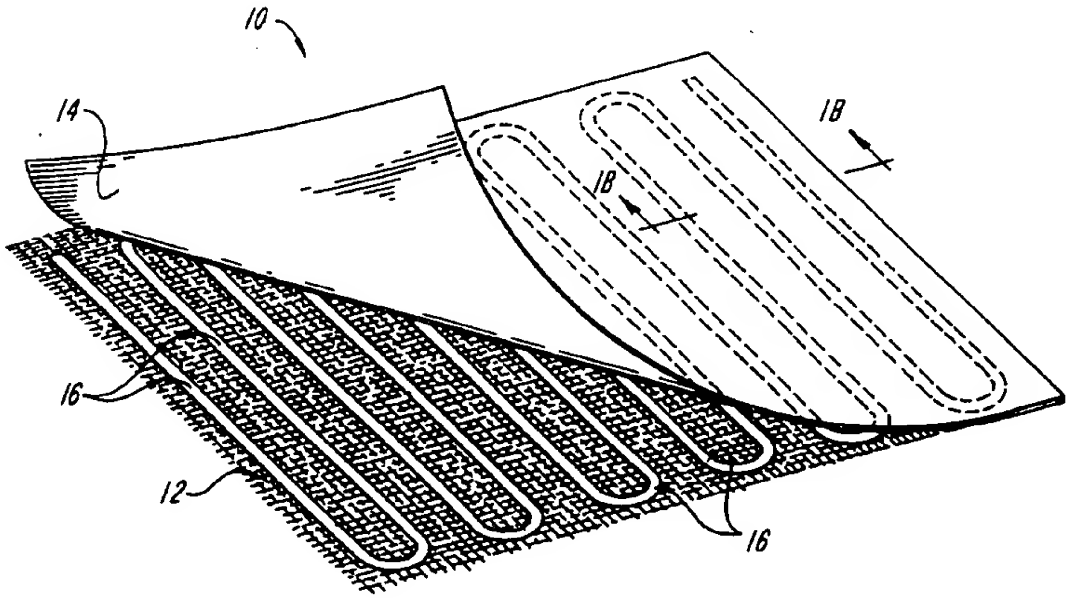
Primary Examiner—Paul B. Prebilic

Attorney, Agent, or Firm—Wolf, Greenfield & Sacks, P.C.

[57] **ABSTRACT**

A composite prosthesis and method for limiting the incidence of postoperative adhesions. The composite includes a mesh fabric and a barrier which prevents exposure of the mesh fabric to areas of potential adhesion. The interstices of the mesh fabric are infiltrated by tissue which secures the prosthesis in place. The composite is positioned with the barrier relative to the region of potential adhesion, such as the abdominal viscera.

5 Claims, 3 Drawing Sheets



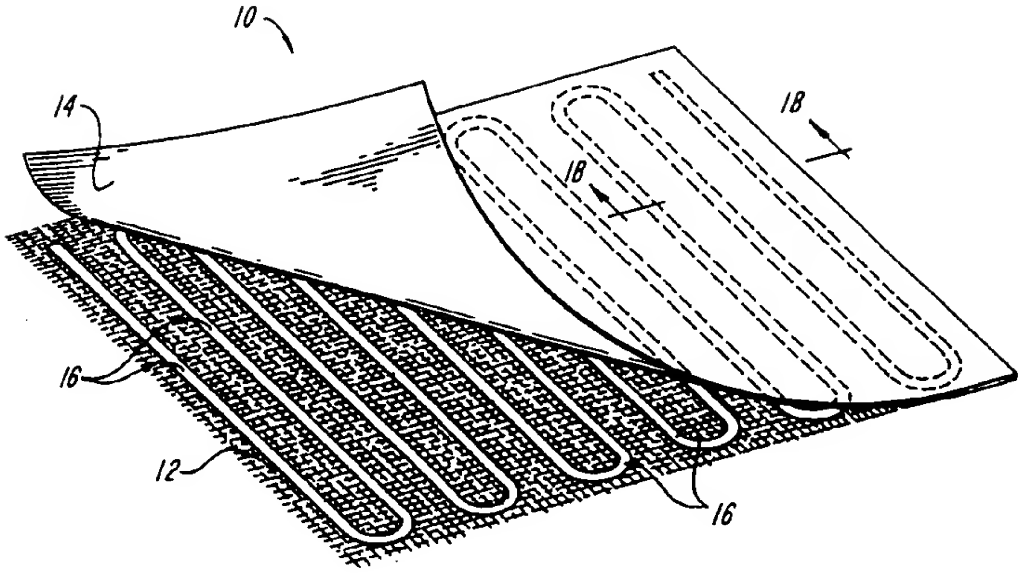


FIG. 1A

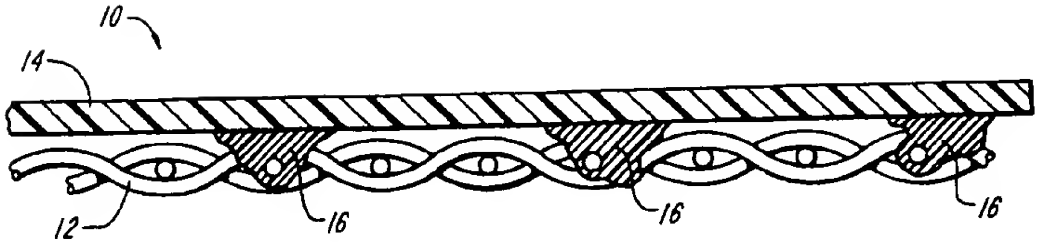


FIG. 1B

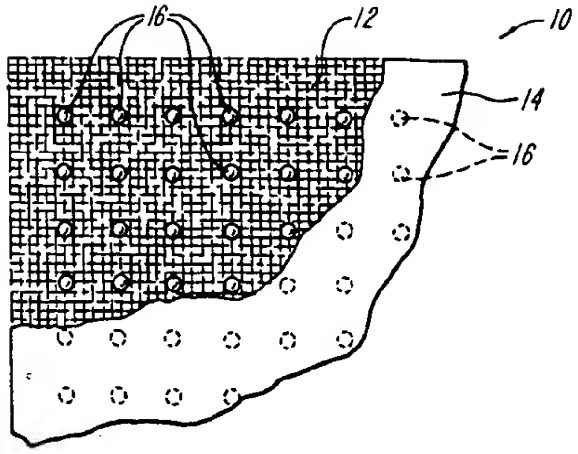


FIG. 2A

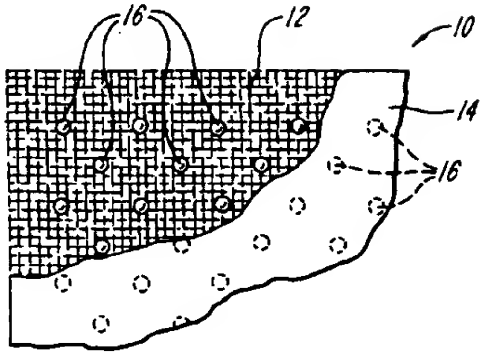


FIG. 2B

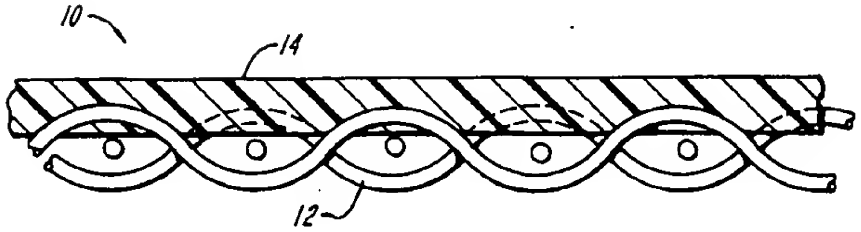


FIG. 3

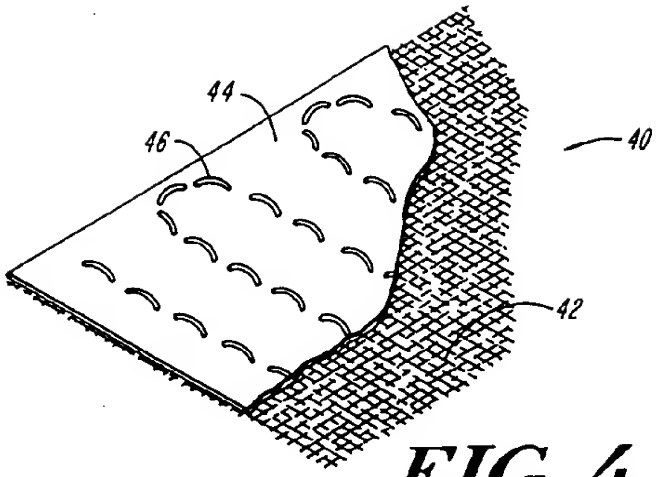


FIG. 4

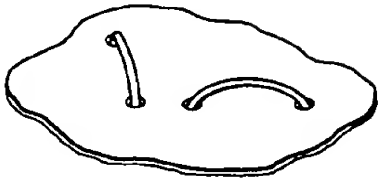


FIG. 5A

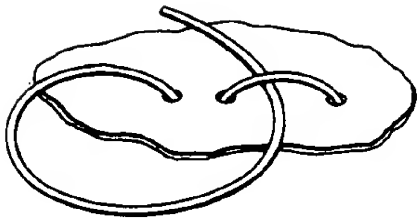


FIG. 5B

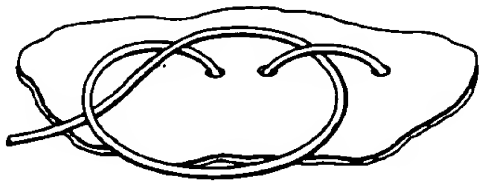


FIG. 5C

METHOD FOR LIMITING THE INCIDENCE OF POSTOPERATIVE ADHESIONS

This application is a continuation of Ser. No. 08/376,735, filed Jan. 23, 1995, now abandoned which is a continuation of Ser. No. 07/846,131, filed Mar. 4, 1992, now abandoned.

FIELD OF INVENTION

The present invention relates to an implantable composite prosthesis and method for limiting the incidence of postoperative adhesions.

BACKGROUND OF THE INVENTION

Various prosthetic mesh materials have been proposed to reinforce the abdominal wall and to close abdominal wall defects. In certain procedures, including incisional and umbilical hernia repair and chest reconstruction, the prosthetic mesh may come into direct contact with the sensitive abdominal viscera. Postoperative adhesions between the mesh and the intestine-may occur, potentially leading to intestinal fistulization.

Various approaches to reducing the incidence of postoperative adhesions arising from the use of prosthetic mesh materials have been proposed by the prior art. It has been suggested to cover the prosthesis with peritoneum or other tissue, where available or adequate to close the defect, to form a biological barrier between the implant and the bowel. Also proposed has been the placement of a physical barrier between the surgical site and the surrounding tissue where adhesions are most commonly encountered.

U.S. Pat. No. 5,002,551 discloses a physical barrier formed of a knitted oxidized regenerated cellulose (Intercede(TC7)). The patent indicates that other physical barriers include silicone elastomers and absorbable gelatin films. Clinical studies of Interceed(TC7) were reported in "Prevention of Postsurgical Adhesions by Interceed(TC7), An Absorbable Adhesion Barrier: A Prospective, Randomized Multicenter Clinical Study", Fertility and Sterility, Vol. 51, No. 6, June 1989, pg. 93–938. Such physical barriers alone are not sufficient to reinforce the abdominal wall or to repair abdominal wall defects.

Jenkins et al., "A Comparison of Prosthetic Materials Used to Repair Abdominal Wall Defects", Surgery, Vol. 94, No. 2, August 1983, pg. 392–398, describes a technique of placing an absorbable gelatin film (Gelfilm®) freely between a piece of Marlex® knitted polypropylene monofilament mesh and the abdominal viscera. The gelatin film dissolved after one week. Thereafter, the incidence of adhesions was reported to be the same as with using the Marlex mesh alone.

Accordingly, the prior art lacks a prosthesis suitable for abdominal wall reconstruction and ventral hernia repair which combines the strength and pliability of a prosthetic mesh with the low incidence of postsurgical adhesions of a physical barrier.

SUMMARY OF THE INVENTION

The present invention is a composite prosthesis and method for reinforcing and repairing a weakened muscular wall while limiting the incidence of postoperative adhesions. The composite is formed of a biologically compatible, flexible and porous implantable material suitable for reinforcing tissue and closing tissue defects, particularly in the abdominal cavity, and a barrier for physically isolating the reinforcing material from areas likely to form adhesions, such as the abdominal viscera. The barrier and implantable material are permanently attached by an adhesive, stitching or insert molding in a manner which preserves sufficient openings in the material for tissue ingrowth.

In one embodiment of the invention, the composite includes attached sheets of knitted polypropylene monofilament mesh fabric and a silicone elastomer. The silicone elastomer is joined to the mesh by an adhesive which encapsulates the yarns of the mesh and bonds to the silicone elastomer. Regular points of attachment between the mesh fabric and the silicone elastomer sheeting provide a strong, integral composite prosthesis.

In another embodiment of the invention, the knitted polypropylene monofilament mesh fabric and silicone elastomer sheeting are sewn together with a polypropylene monofilament yarn. The knots are located on the mesh side of the prosthesis to minimize the exposure of the monofilament yarn to the areas of potential adhesion.

In a further embodiment of the invention, the silicone elastomer is insert molded to the mesh. The impregnation of the mesh by the molded silicone elastomer is limited to preserve sufficient openings in the mesh for tissue infiltration.

It is among the general objects of the invention to provide a prosthesis which combines the attributes of a surgical mesh fabric and of a physical barrier.

It is a further object of the invention to provide a prosthesis for repairing ventral hernias and for reconstructing the chest wall which limits the incidence of postoperative adhesions and intestinal fistulization.

It is a further object of the invention to provide a prosthesis which stimulates tissue infiltration without causing a similar inflammatory response of the abdominal viscera.

It is a further object of the invention to provide a prosthesis which may be custom shaped, sized and affixed during surgery without destroying the integrity of the device.

An additional object of the invention is to provide a prosthesis which is sufficiently flexible to conform to the surgical site.

Other objects and features of the present invention will become apparent from the following detailed description when taken in connection with the accompanying drawings which disclose multiple embodiments of the invention. It is to be understood that the drawings are designed for the purpose of illustration only and are not intended as a definition of the limits of the invention.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following drawings in which:

FIG. 1(*a*) is an illustration of the implantable composite prosthesis according to the present invention showing the serpentine pattern of adhesive;

FIG. 1(*b*) is a sectional illustration along line 1(*b*) of FIG. 1(*a*);

FIG. 2(*a*)–(*b*) are illustrations of adhesive patterns for joining the mesh fabric and the barrier sheeting;

FIG. 3 is a sectional illustration of an insert molded implantable composite prosthesis according to the present invention;

FIG. 4 is an illustration of a stitched implantable composite prosthesis according to the present invention; and

FIG. 5 is an illustration of a "blind hem stitch" for assembling the implantable composite prosthesis shown in FIG. 4.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The composite prosthesis **10** for limiting the incidence of postoperative adhesions shown in FIGS. 1(*a*)–(*b*) includes a tissue infiltratable fabric **12** and an adhesion barrier **14**. The fabric is formed of a material which stimulates an inflammatory reaction in tissue after implantation and includes a plurality of openings which allow sufficient tissue ingrowth to secure the composite to host tissue. The barrier separates the fabric from the area of potential tissue adhesion. In the repair of ventral hernias and in chest wall reconstruction, the barrier isolates the abdominal viscera from the fabric, preventing intestinal adhesion and fistulization which may result from an inflammatory reaction of the bowel and the prosthetic mesh. The composite combines the strength, handling and fibroblastic stimulation of a prosthetic mesh with the low adhesion incidence of a physical barrier.

The relatively flat composite prosthesis sheet is sufficiently pliable to allow the surgeon to manipulate the shape of the implant to conform to the anatomical site of interest and to be sutured or stapled there. Alternatively, the composite may be pre-formed into a more complex shape, such as a tapered plug for filling and occluding a ruptured wall. The barrier need only cover that portion of the implant which is likely to be exposed to the intestine. The shape and size of the composite implant, and of the respective fabric and barrier, may vary according to the surgical application as would be apparent to those of skill in the art.

The tissue infiltratable fabric **12** includes a plurality of interstices or pores which are of sufficient size and orientation to allow tissue ingrowth. The barrier **14** is connected to the fabric **12** without detrimentally limiting the tissue infiltration. The barrier **14** preferably is formed of a translucent material which allows the physician to observe the location and integrity of the composite prosthesis during implantation. Holes may be formed through the barrier **14** to facilitate passage of neutrophiclic graneulocytes, reducing the incidence of infection. The holes should have dimensions sufficient to permit neutrophilic graneulocytic transport without detrimentally affecting the adhesion resistance of the composite.

The mesh fabric **12** and barrier **14** are integrally connected by an adhesive layer **16**. A preferable serpentine pattern of adhesive is illustrated in FIG. **1** which provides a high density of points of attachment between the cover **14** and fabric **12** while still maintaining a sufficient quantity of open or non-impregnated interstices for tissue infiltration. The serpentine pattern maintains composite integrity by preventing the barrier and underlying fabric from separating if the prosthesis is custom cut by the surgeon to match a particular anatomical site.

Alternatively, the adhesive may be applied in a grid-like pattern of dots or beads. In a representative arrangement, one and a half millimeter diameter dots with one centimeter uniform spacing form an effective joint between the fabric and the barrier. A pattern of uniformly spaced beads is shown in FIG. 2(*a*). A staggered configuration is shown in FIG. 2(*b*). Various other shapes, sizes and patterns of adhesive may be used as would be apparent to those of skill in the art.

The fabric **12** preferably is formed of a sheet of knitted polypropylene monofilament mesh fabric such as Marlex® mesh available from C. R. Bard, Inc. When implanted, the polypropylene mesh stimulates an inflammatory reaction which promotes rapid tissue ingrowth into and around the mesh structure. Alternatively, other surgical materials which are suitable for tissue reinforcement and defect closure may be utilized including Prolene®, Dacron®, Teflon® and Merselene®. Absorbable meshes, including polyglactin (Vicryl®) and polyglycolic acid (Dexon®), may be suitable for applications involving temporary repair of fascial defects. It also is contemplated that the mesh fabric may be formed from multifilament yarns and that woven, molded and other recognized methods of forming prosthetic mesh materials would be suitable.

The barrier **14** preferably is formed from a sheet of silicone elastomer such as Silastic® Rx Medical Grade Sheeting (Platinum Cured) distributed by Dow Corning Corporation. Silastic® does not substantially stimulate adhesion formation when implanted in tissue and is significantly less likely to cause an inflammatory reaction with neighboring tissue than would a prosthetic mesh. The silicone elastomer sheeting may be reinforced with Dacron® or other reinforcing materials. Other adhesion resistant materials also may be used as would be apparent to those of skill in the art. It is contemplated that Teflon® mesh, microporous polypropylene sheeting (Celgard®), expanded PTFE (Gorerex®) and oxidized, regenerated cellulose (Intercede(TC7)) alternatively may be used as barriers to adhesion and erosion. However, a composite formed of Intercede(TC7) may have only short term effectiveness, the Intercede(TC7) barrier being absorbed only a short period after implantation.

A preferred adhesive **16** for joining the silicone elastomer barrier to the knitted monofilament polypropylene mesh fabric is Silastic® Medical Adhesive Type A available from Dow Corning Corporation. The Silastic Medical Adhesive Type A forms a matrix which encapsulates the knitted polypropylene monofilament mesh fabric and bonds to the silicone elastomer sheet. Other adhesives may be utilized as would be apparent to those of skill in the art, the ultimate selection depending upon the composition of the fabric and the barrier.

A preferred procedure for applying the adhesive involves securing overlayed sheets of Marlex® knitted polypropylene monofilament mesh fabric and Silastic® silicone elastomer in a embroidery type hoop frame which includes an inner hoop, a variable diameter outer hoop and a hoop tightening mechanism. The Marlex® mesh and Silastic® sheets are pulled away from the hoops until sufficiently taut. It may be advantageous to stretch the mesh first and then the sheet of silicone elastomer to prevent pucking or wrinkling of the materials.

The frame is then secured on a positioning table of a liquid dispensing apparatus, such as the CAM/ALOT Model 1414 available from Camelot Systems, Inc. of Haverhill, Mass., with the mesh side facing the adhesive applicator. The adhesive is deposited under appropriate temperature and pressure through an appropriately sized needle positioned against the mesh surface so that the adhesive passes into the mesh interstices and against the bottom face of the silicone elastomer barrier. The deposition of the adhesive is computer controlled allowing the adhesive pattern (serpentine, spaced dots, etc.) to be pre-programmed.

In a representative embodiment, the composite includes a 10 inch by 14 inch sheet of Marlex® mesh knit from Marlex® polypropylene monofilament with a 0.006 inch diameter. A similarly sized 0.005 inch thick sheet of vulcanized silicone elastomer (Silastic®) is attached to the mesh

with a serpentine pattern of 0.125 inch wide beads of adhesive (Silastic® Medical Adhesive A).

A molded composite prosthesis **30** is illustrated in FIG. 3 and includes a prosthetic mesh substrate **32** which has been insert molded to a silicone elastomer barrier **34**. The silicone elastomer does not completely impregnate the mesh interstices, preserving sufficient openings for tissue infiltration. Holes **36**, which may be formed by upstanding pins in the mold, extend completely through the silicone elastomer barrier to provide a pathway for bacteria. The mesh fabric may be surface treated with a carbon dioxide plasma etch prior to molding which may enhance the union of the mesh and the silicone elastomer.

In a representative procedure, a Silastic® Q7-2213 Implant Grade Dispersion available from Dow Corning Corporation was poured into a mold with excess material being removed with a wooden spatula. A sheet of Marlex® mesh fabric was pressed into the mold until the pins impinged the knitted mesh. The solvent was evaporated in a chemical hood and then the dispersion was cured for one hour at 120° C.

A stitched composite prosthesis **40** is illustrated in FIG. **4** and includes sheets of knitted polypropylene monofilament mesh fabric **42** and of a silicone elastomer **44** which are sewn together with a monofilament polypropylene yarn **46**. The preferable stitching pattern ("blind hem stitch") illustrated in FIG. **5** ensures that the knots are formed on the mesh fabric side of the composite rather than on the elastomer side where they may cause localized adhesions with the bowel. In a representative embodiment, 0.5 to 1.0 centimeters long "blind hem" stitches were formed with a 0.006 inch diameter polypropylene monofilament and spaced every 0.5 to 1.0 centimeters, with seams spaced every 0.5 to 1.0 centimeters. A frame consisting of a flat bottom plate and a flat top plate with matching rectangular windows was used to hold the sheets of mesh and silicone elastomer during the sewing procedure.

A comparison of the composite prosthesis and a prosthesis consisting of Marlex® mesh alone has been made in rabbit and rat studies.

In the rabbit study, 4 cmx6 cm defects were created on each side of the abdominal wall muscle and peritoneum. The defects were patched by intraperitoneal placement in each rabbit of respective 5 cmx7 cm pieces of Marlex mesh and a composite prosthesis (opposing flat pieces of Marlex® mesh fabric and Silastic® joined by stitching with a "blind hem stitch"). The patches were attached to the inner face of the abdominal wall by 4-0 Prolene sutures. The incision was closed and the animals permitted to recover. After 24 to 34 weeks, the rabbits were sacrificed and examined.

Postoperative adhesions between the Marlex® mesh and the intestine were observed. No intestinal adhesions were observed with the composite prosthesis. The composite was observed to be completely anchored to the abdominal wall and infiltrated by host tissue.

In the rat study, mesh samples were placed between the liver and the inner peritoneal wall. The peritoneum, abdominal rectus muscle and skin were sutured closed with Ethicon 2-0 silk. The rats were sacrificed after six days and the implantation site exposed. An Instron test machine, Model 1123, was used to pull the implanted prostheses from the exposed site at a constant speed of 5 mm/min. The relative tensile force required to withdraw the prosthesis from the implant site is believed to correlate to the severity of postoperative adhesions. The test indicated that almost double the relative tensile force was required to extract the Marlex mesh implant than was required to remove the composite prosthesis.

The present invention therefore provides a prosthetic implant, amongst which are certain of the following advantages. The composite prosthesis combines the strength of a mesh material and the low adhesion incidence of a physical barrier. The composite may be anchored in place by tissue ingrowth through the mesh interstices. The specific pattern of attachment (adhesive, molding, stitching, etc.) of the mesh fabric and barrier provides a dimensionally strong implant without detrimentally affecting tissue infiltration.

The composite of the present invention is particularly indicated for repair of ventral hernias (incisional and umbilical) and chest wall defects where it is more common for the prosthetic mesh to be exposed to the abdominal viscera due to insufficient or unavailable autogenous tissue. The non-inflammatory silicone elastomer barrier prevents the mesh fabric from contacting the abdominal viscera, reducing the incidence of intestinal adhesion and fistulization. It also is contemplated that the composite prosthesis would be indicated for use in laparoscopic procedures, particularly intraperitoneal applications where the peritoneum would not be available to provide a natural barrier between the implant and the intestine.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other equivalents, embodiments and modifications of the invention may be apparent to those skilled in the art.

We claim:

1. A method for limiting the incidence of postoperative adhesions arising from a repair of an opening in a tissue or muscle wall, wherein the opening is located near a region of potential postoperative adhesion, comprising:

providing a composite prosthesis including an implantable material constructed and arranged to occlude the opening and having a plurality of interstices constructed and arranged to allow tissue ingrowth, and a barrier which does not substantially stimulate the formation of postoperative adhesions, the barrier covering the implantable material, whereby the composite prosthesis is securable in place by growth of neighboring tissue into the implantable material; and

positioning the composite prosthesis for limiting the formation of postoperative adhesions with the implantable material filling or covering, thereby occluding, the tissue or muscle wall opening, and with the barrier facing away from the tissue or muscle wall opening and extending between the region of potential postoperative adhesion and the implantable material.

2. The method recited in claim **1** wherein the implantable material stimulates an inflammatory reaction when implanted in tissue.

3. The method recited in claim **1** wherein said positioning step includes positioning the composite prosthesis with the implantable material extending across the opening to the tissue or muscle wall.

4. The method recited in claim **1** wherein the repair is a chest wall reconstruction.

5. The method recited in claim **1** wherein the repair is a ventral hernia repair.

* * * * *

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 8-5 (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9301 for regular communications and 703-872-9301 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
May 7, 2003

US006267772B1

(12) **United States Patent**
Mulhauser et al.

(10) **Patent No.: US 6,267,772 B1**
(45) **Date of Patent: Jul. 31, 2001**

(54) **IMPLANTABLE PROSTHESIS**

(75) Inventors: **Paul J. Mulhauser**, New York, NY (US); **Paul C. DiCesare**, Norwalk, CT (US)

(73) Assignee: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/291,651**

(22) Filed: **Apr. 6, 1999**

Related U.S. Application Data

(62) Division of application No. 08/250,657, filed on May 27, 1994, which is a continuation of application No. 07/886,689, filed on May 20, 1992, now abandoned.

(51) **Int. Cl.**[7] **A61B 17/00**; A61F 2/00
(52) **U.S. Cl.** **606/151**; 623/11.11
(58) **Field of Search** 623/1.21, 11.11; 606/108, 193, 151; 424/426, 424; 602/46, 904, 44, 58

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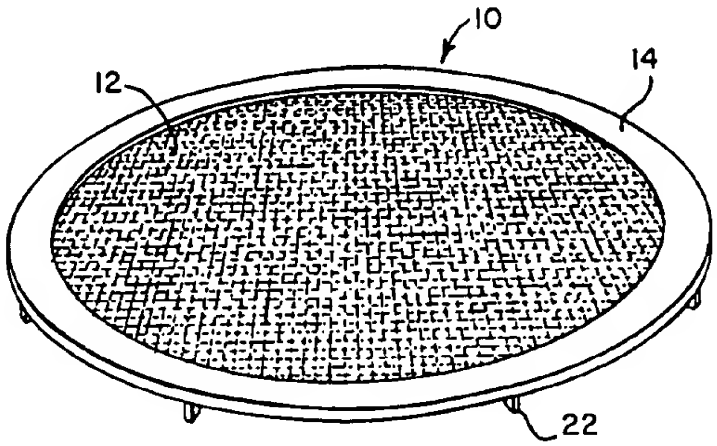
Primary Examiner—David J. Isabella
(74) *Attorney, Agent, or Firm*—Wolf, Greenfield & Sacks, P.C.

(57) **ABSTRACT**

An implantable prosthesis for occluding the opening of a muscle or tissue defect. The implant is laparoscopically deliverable with a system for loading and delivering the prosthesis through a trocar cannula. The prosthesis includes an implantable material with a body portion sufficient to extend across and occlude a defect opening. Antimigration barbs extend from the implantable material to prevent migration of the prosthesis after implantation. A semi-rigid ring may be attached to the material for supporting the body portion. The barbs may be located on the ring. The implantable prosthesis may be provided with a sufficient hoop strength to prevent the body portion from collapsing into the defect opening.

40 Claims, 11 Drawing Sheets



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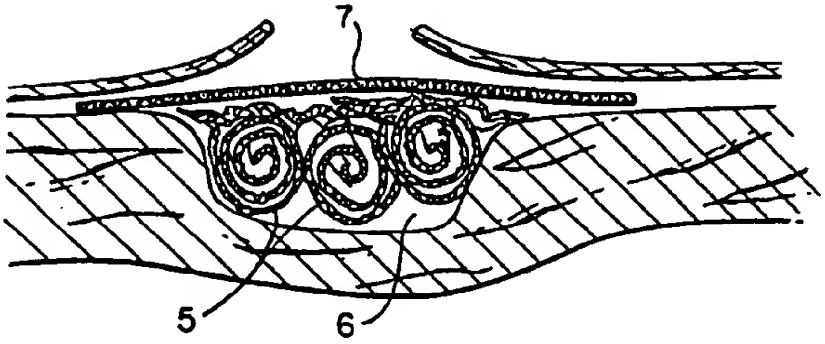


Fig. 1
(PRIOR ART)

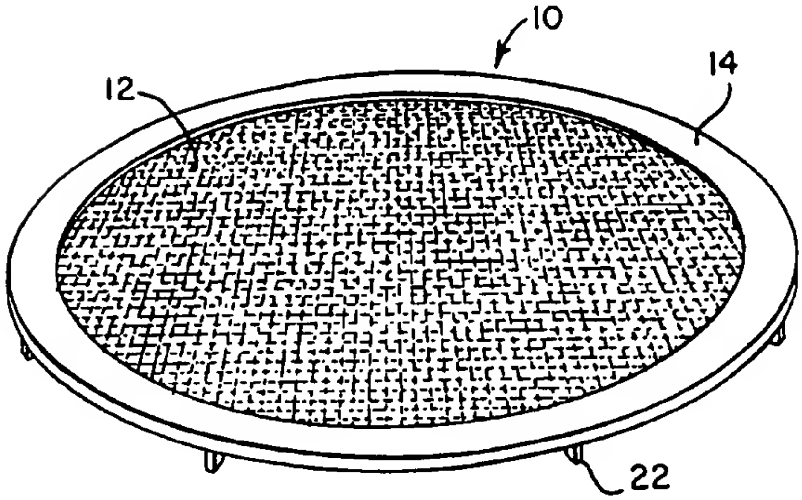


Fig. 2(a)

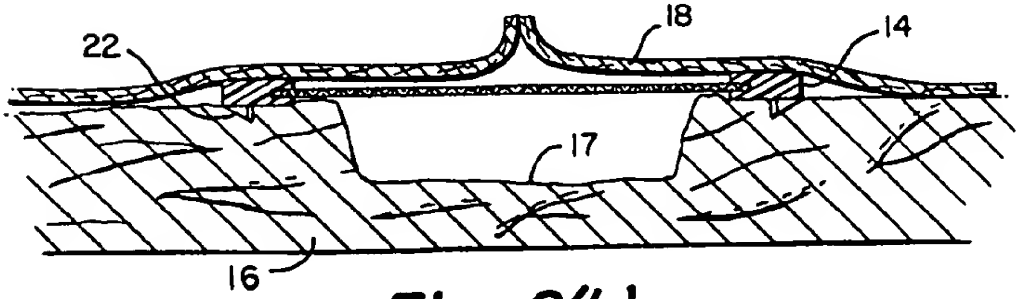


Fig. 2(b)

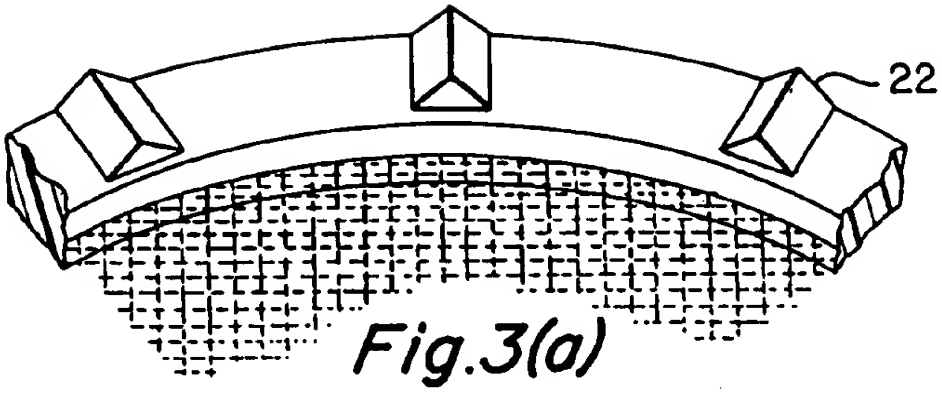
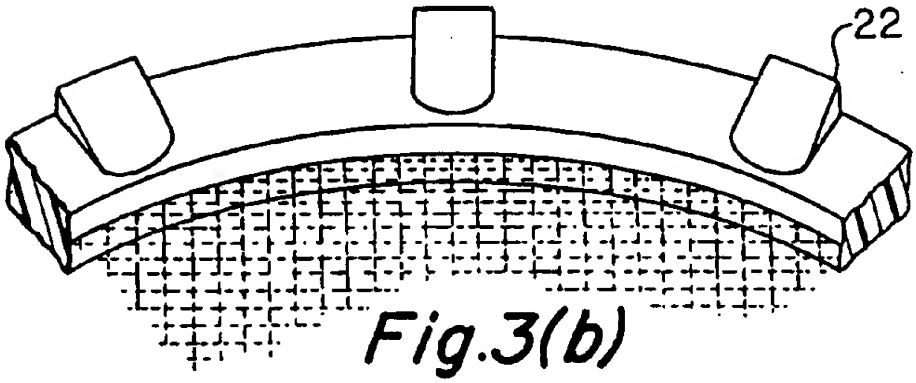


Fig.3(a)



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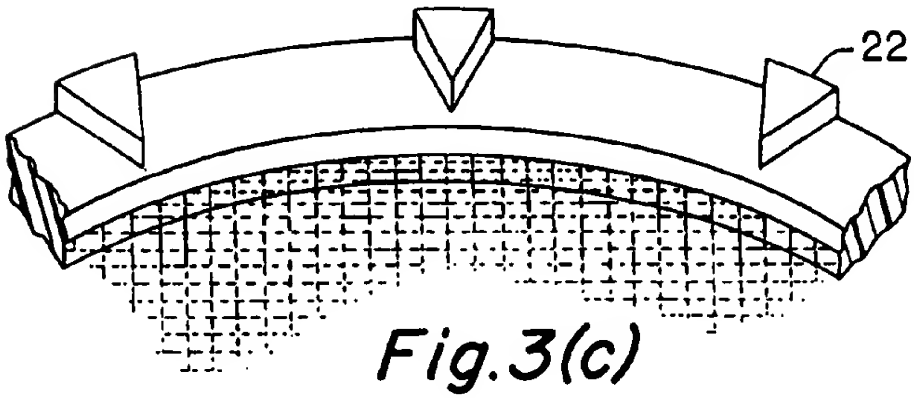
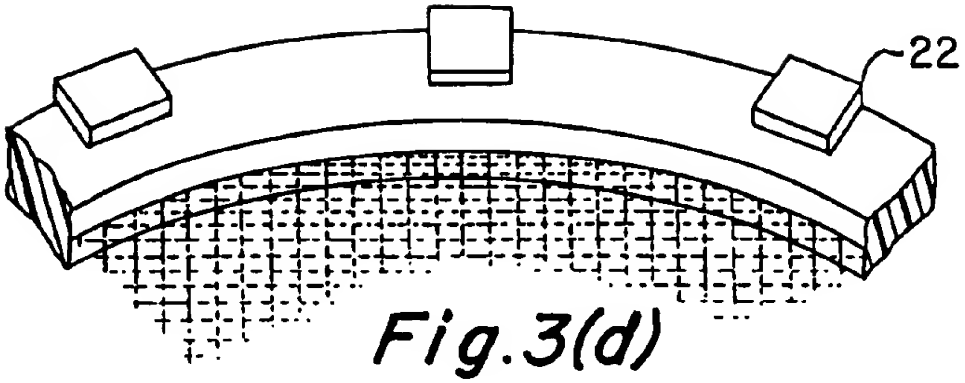


Fig.3(c)



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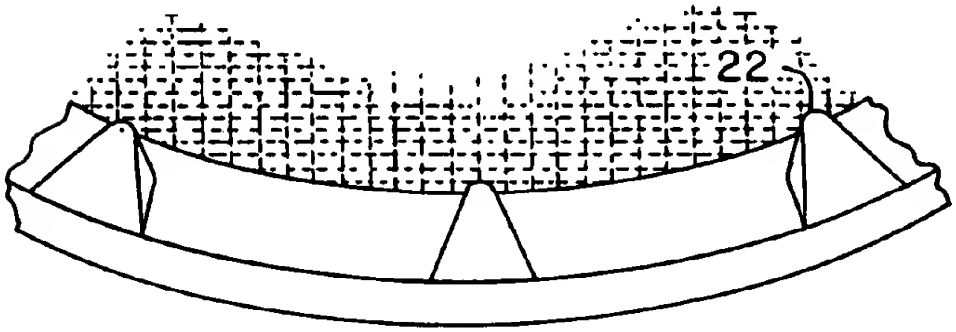

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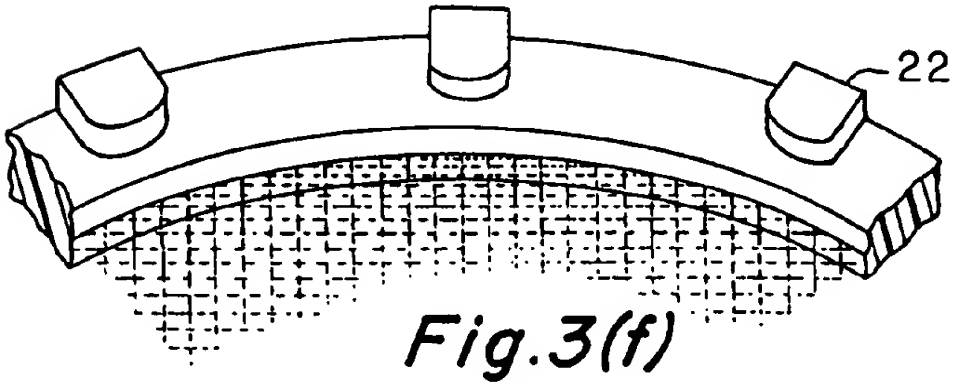

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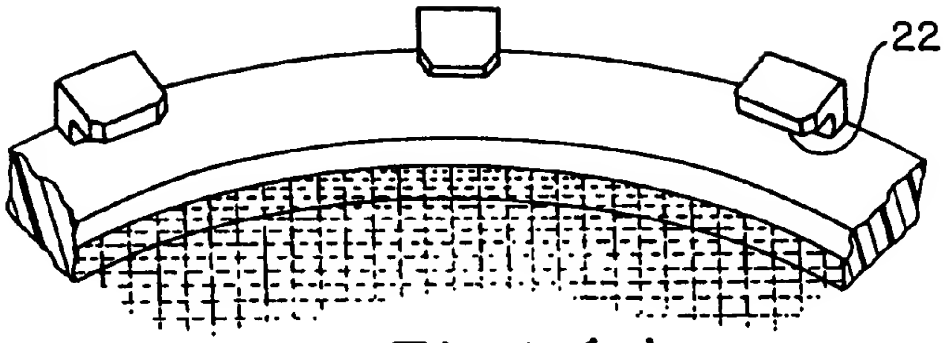

Fig.3(g)

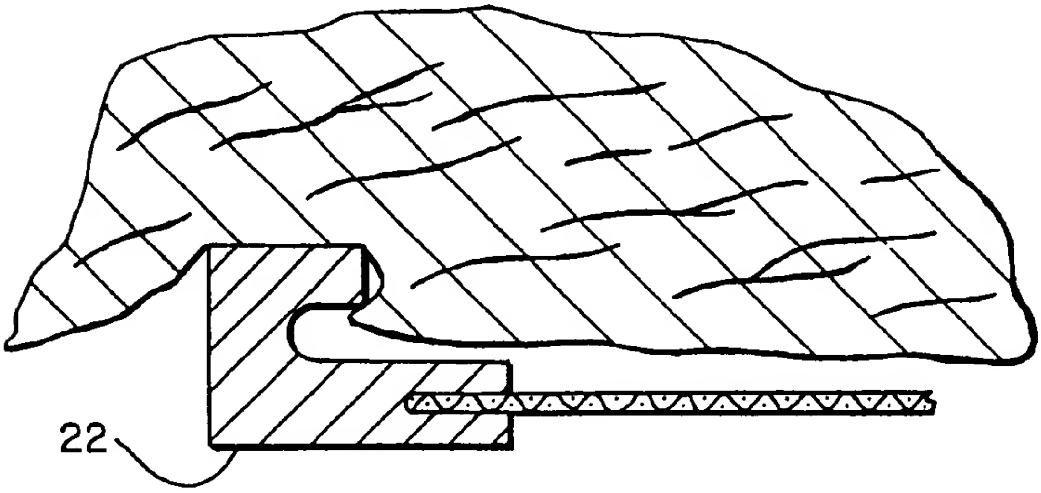

Fig.3(h)

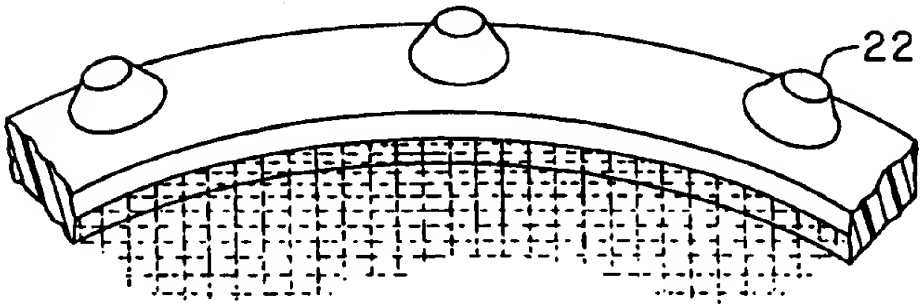

Fig.3(i)

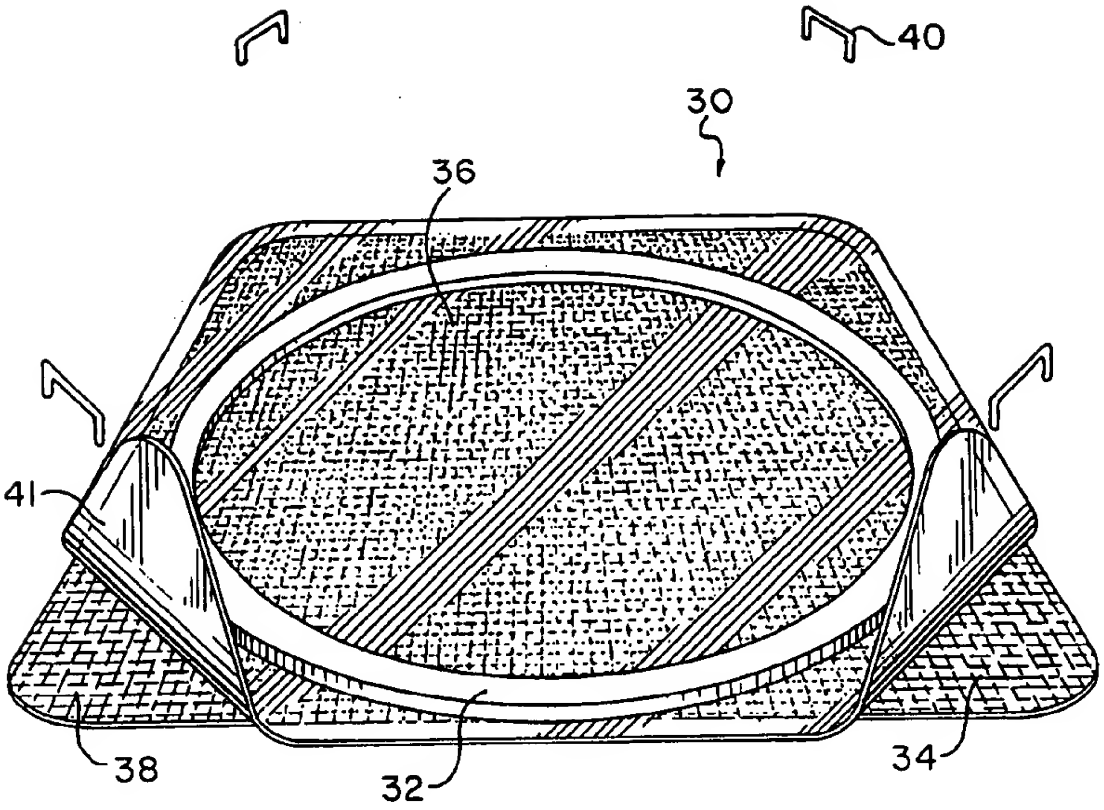

Fig. 4(a)

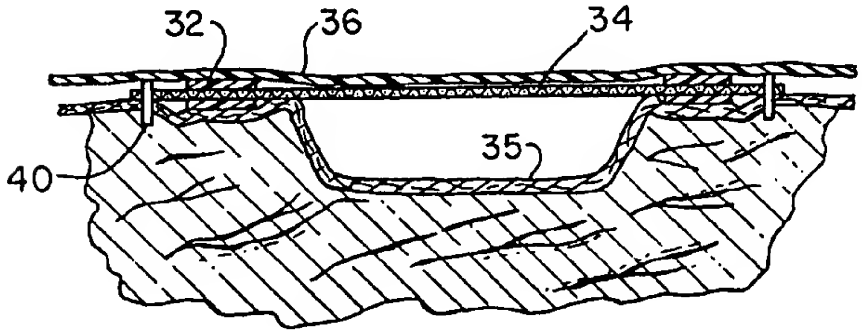

Fig. 4(b)

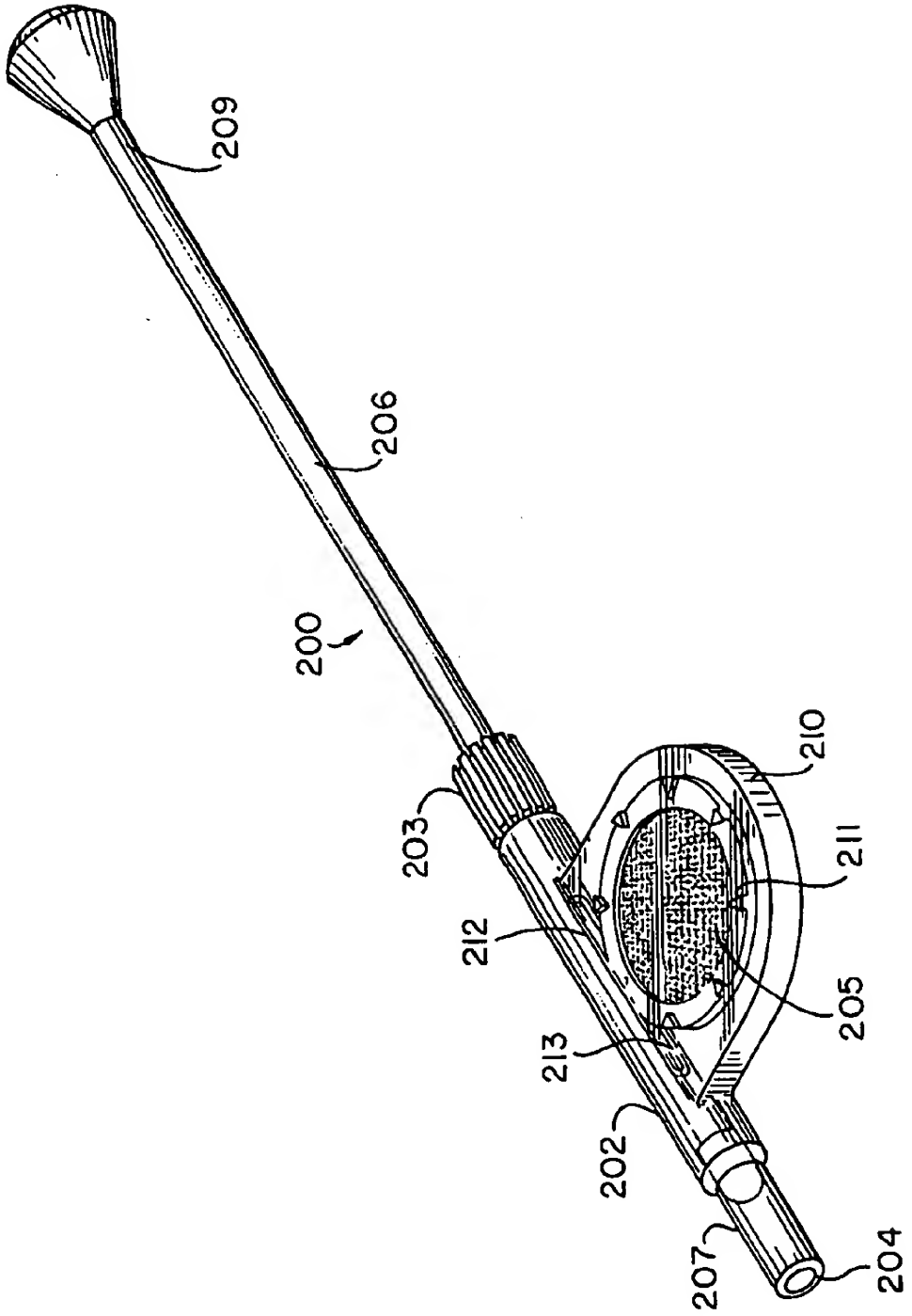

Fig.5(a)

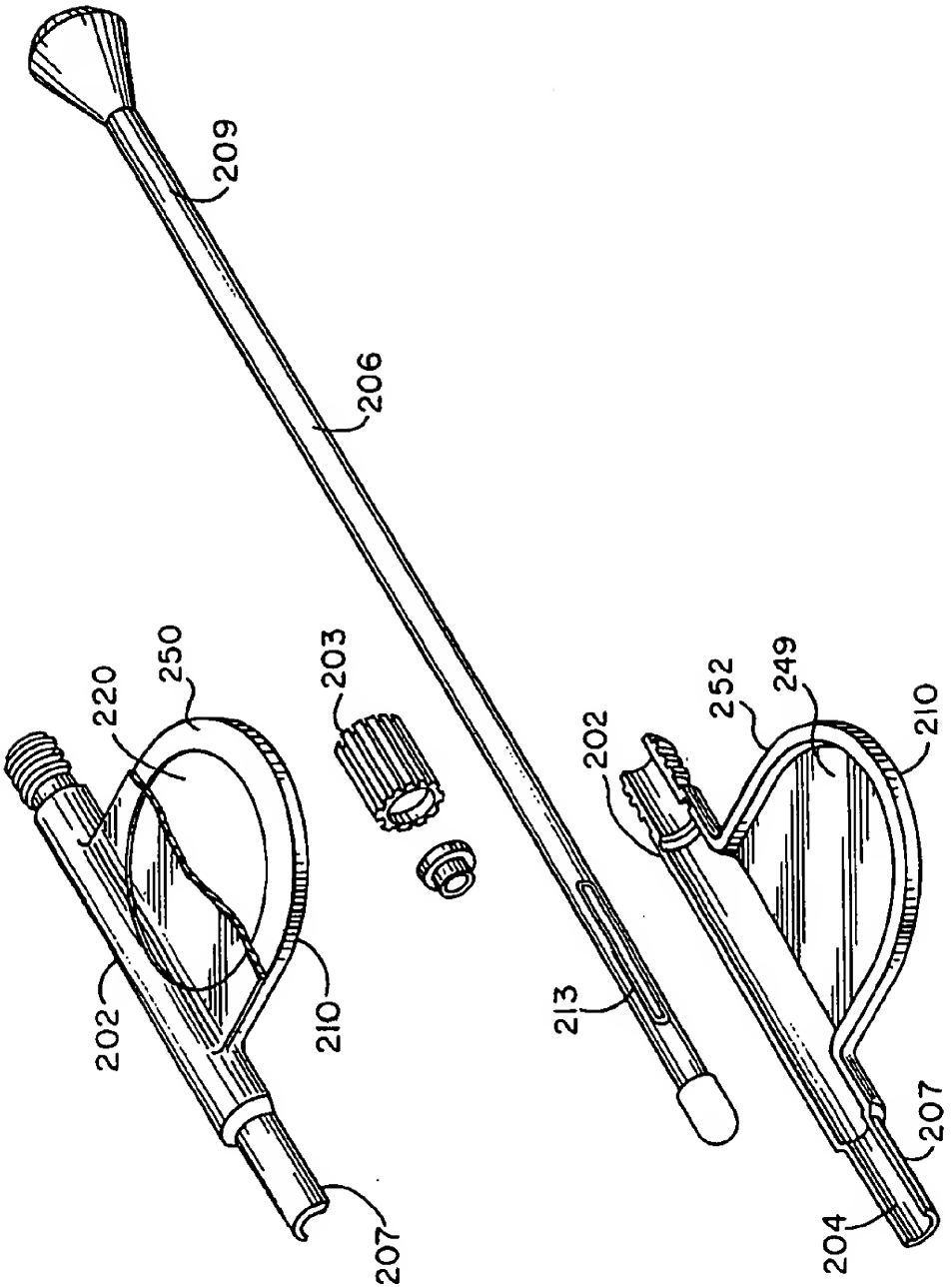

Fig.5(b)

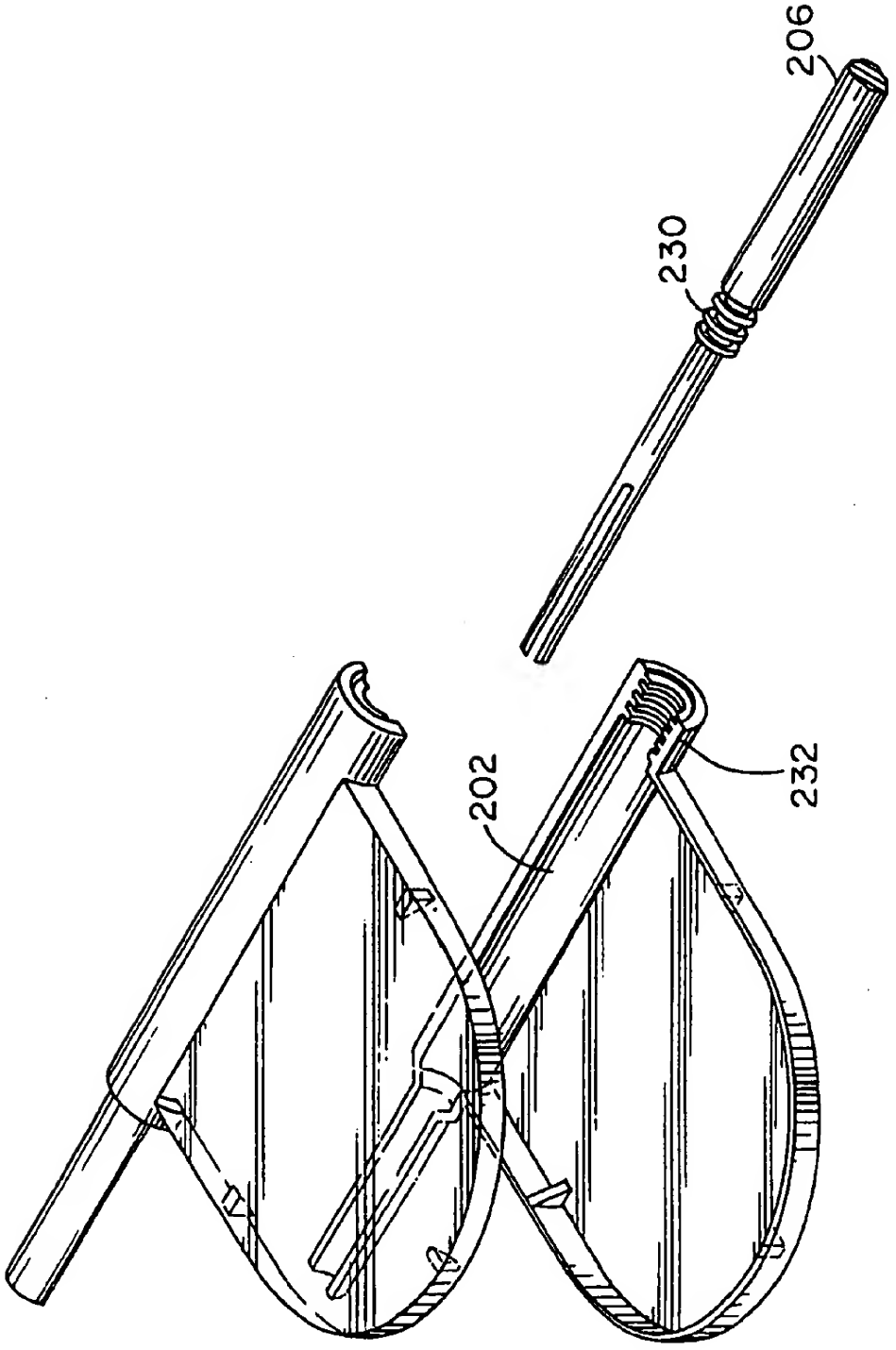

Fig. 6

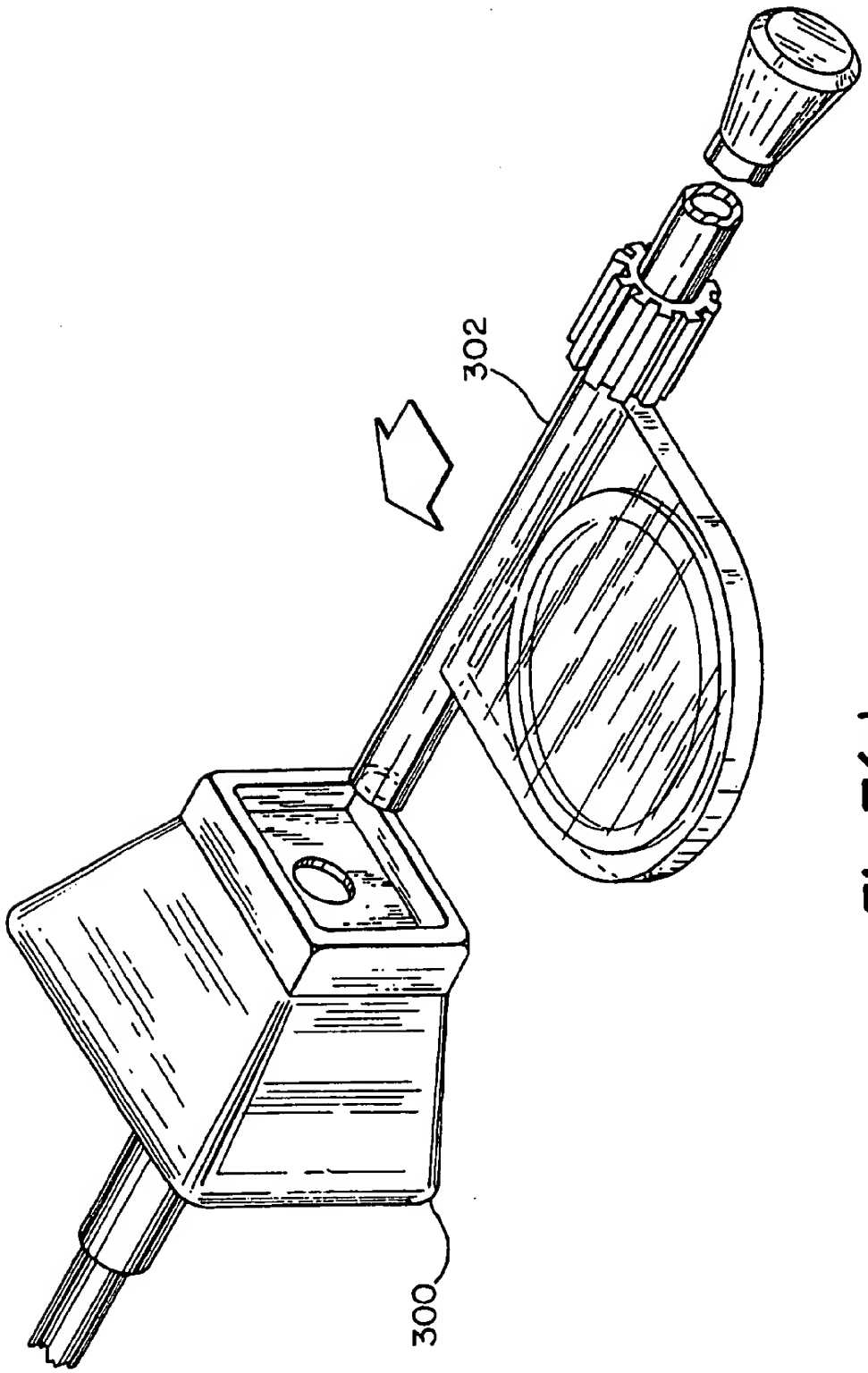

Fig. 7(a)

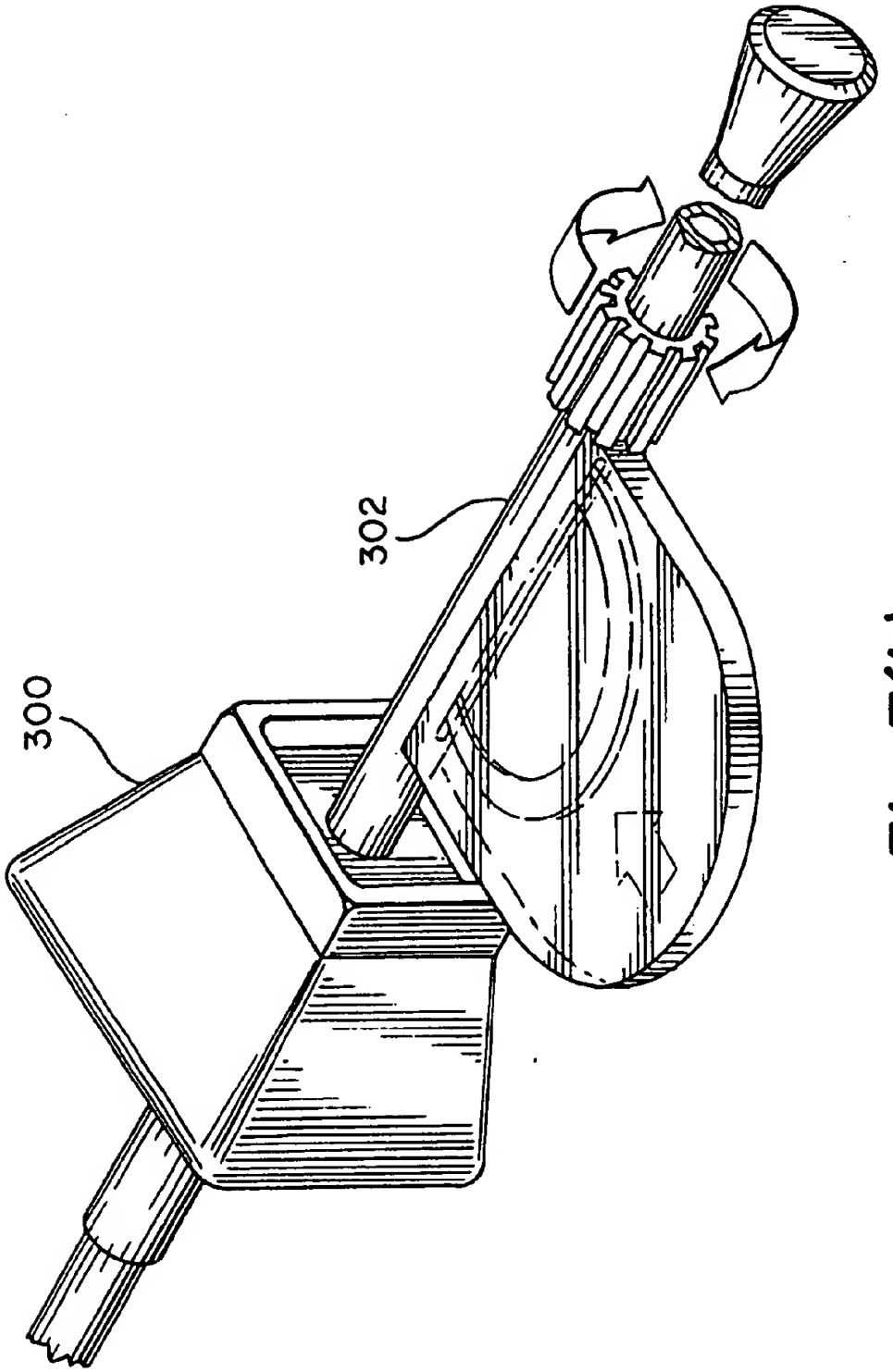

Fig. 7(b)

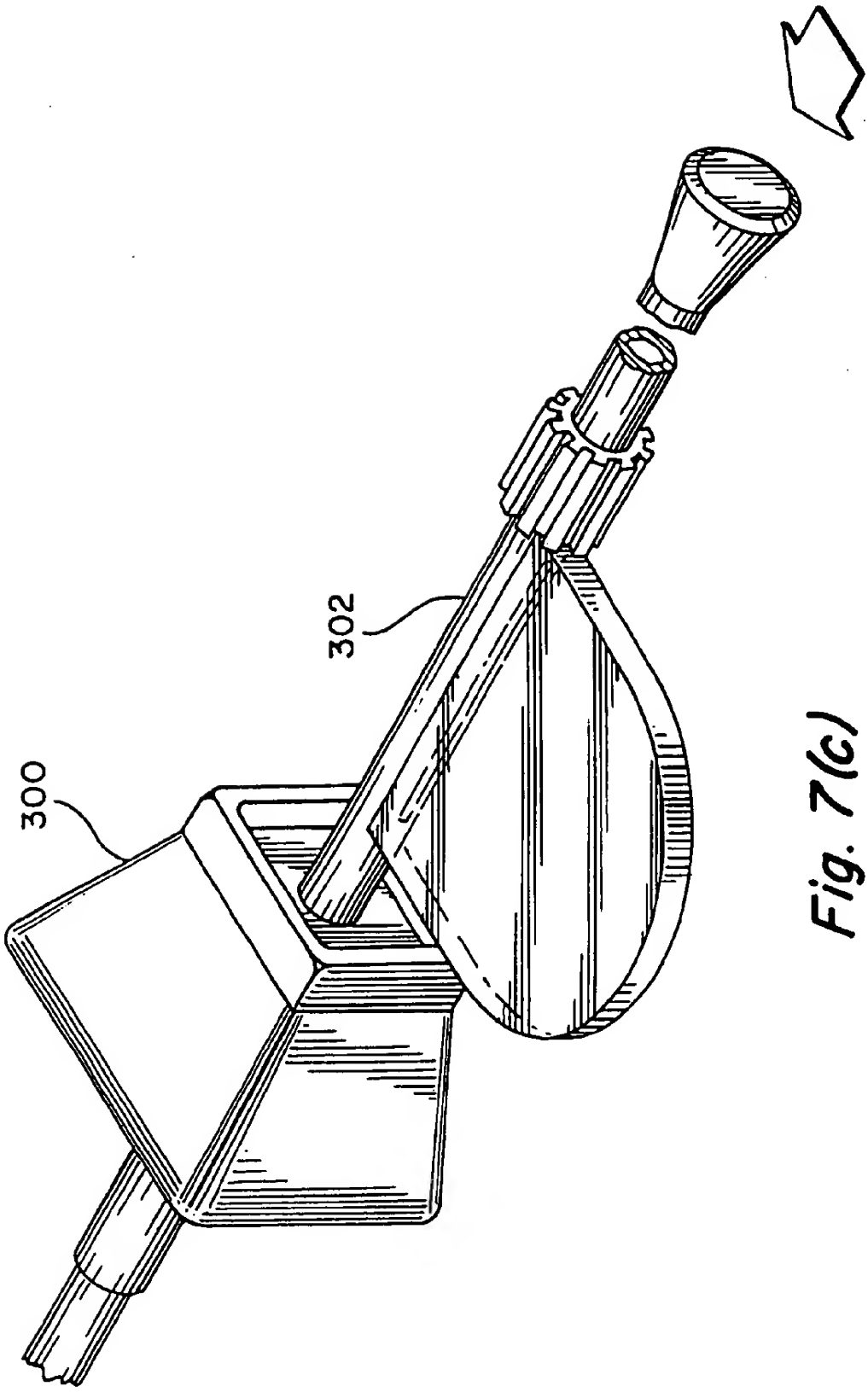

Fig. 7(c)

IMPLANTABLE PROSTHESIS

RELATED U.S. APPLICATION DATA

This application is a division of application Ser. No. 08/250,657, filed May 27, 1994, now pending, which is a continuation of application Ser. No. 07/886,689, filed May 20, 1992, now abandoned.

FIELD OF INVENTION

The present invention relates to an implantable prosthesis for occluding the opening of a muscle or tissue defect.

BACKGROUND OF THE INVENTION

Various implants have been proposed for repairing abdominal wall defects such as direct and indirect inguinal hernias. Inguinal hernias occur when the peritoneum (lining of the abdominal cavity) and bowel pass into the inguinal canal through a hole in the innermost muscle layer called the transversalis fascia. An indirect hernia forms when a portion of the intestine passes through the internal ring and courses obliquely down the inguinal canal. A direct hernia involves the rupture of the inguinal canal floor adjacent the internal ring. An indirect hernia is marked by a long tubeshaped defect while a direct hernia is identified by a shallow hole.

Classical repair of inguinal hernias (reparative herniorrhaphy) requires a two inch or longer incision through the abdominal wall. The many layers of healthy tissue are then retracted by the physician to expose the void. The healthy muscle and tissue which have been incised to reach the rupture site require a long period of recovery (six days or longer) and result in substantial postoperative pain.

A laparoscopic hernia repair technique recently proposed uses an illuminating optical instrument (laparoscope) which is inserted through a thin tube (trocar cannula) in the abdominal wall to visualize the interior of the abdominal cavity. The entire surgical procedure takes place using special surgical tools manipulated through additional cannulae extending through the abdominal wall. Laparoscopic surgery minimizes patient discomfort and recovery time, allows diagnosis without invasive surgery and lessens the risk of traumatic injury to the abdominal tissues.

Various mesh prostheses have been proposed for use in laparoscopic hernia repair. Representative are the mesh fabric logs or plugs **5** illustrated in FIG. **1** which are formed by rolling sheets of mesh into cylinders and then suturing the ends. The logs are inserted into the defect **6** until the void is filled. A larger flat piece of mesh **7**, commonly referred to as an onlay patch, is placed over the herniated opening, holding the logs in place. The mesh materials become bound in place as tissue grows through the fabric.

The use of mesh logs or plugs may suffer from certain deficiencies. Overstuffing of the void may lead to occlusion of a testicular vessel and, potentially, testicular swelling or atrophy. Further, the mesh logs may cause a bulky protrusion which the patient can feel, although the sensation should decrease over time. Lastly, the use of customized plugs and logs does not lend itself to a standardized surgical procedure.

A composite mesh prosthesis suitable for use in classical and laparoscopic surgery is disclosed in commonly assigned U.S. Pat. No. 5,593,441 issued to Lichtenstein et al., entitled "Method For Limiting The Incidence Of Postoperative Adhesions", the disclosure of which is specifically incorporated herein by reference. The composite implant includes a tissue infiltratable fabric and an adhesion barrier which isolates the inflammatory mesh from sensitive tissue such as the abdominal viscera.

Various tools have been proposed in the art for loading and delivering the mesh implants through the trocar cannula and into the abdominal cavity. In the case of the mesh logs, typically one end of the log is held by a grasper which is then retracted into the lumen of an introducer tube. The rear-end loaded introducer and grasper are inserted into and through the trocar cannula. That technique may have certain disadvantages including the need to coordinate a separate introducer and grasper instrument to collapse the implant and then deliver the implant to the hernia site.

Accordingly, the prior art lacks a mesh implant suitable for laparoscopic repair which effectively occludes the hernia defect without stuffing the void. The prior art also lacks a single and efficient tool for collapsing and delivering an implant through a trocar cannula to a defect site.

SUMMARY OF THE INVENTION

The present invention is a prosthesis that may be laparoscopically implanted with a system for loading and delivering the prosthesis through a laparoscopic cannula. The implantable prosthesis is formed of a biologically compatible, flexible implantable material suitable for reinforcing tissue and closing tissue defects, particularly in the abdominal cavity. The prosthesis may include a semi-rigid ring which supports the material in a predetermined shape, improving handleability. The ring also imparts sufficient hoop strength to the implant, preventing the material from collapsing into the rupture site after emplacement.

In one embodiment of the invention, the implant includes a piece of knitted polypropylene monofilament mesh fabric having antimigration barbs extending therefrom to prevent movement of the implant as the tissue grows through the mesh. The mesh fabric may be attached to a ring of polypropylene with the antimigration barbs located on the bottom of the ring.

In another embodiment of the invention, spaced portions of mesh extend beyond the ring providing sites for stapling to healthy tissue surrounding the herniated area.

In a further embodiment, the mesh is covered with a barrier material which isolates the inflammatory fabric from sensitive tissue such as the abdominal viscera. The edges of the barrier material overlying the mesh fabric are liftable, allowing the underlying anchoring portions of mesh to be secured to neighboring tissue.

The present invention also includes a device for loading and delivering the mesh implant to a trocar cannula emplaced in the abdominal cavity. A main body is provided with a lumen for reducing the implant into a narrower cylindrical configuration. An introducer shaft winds the implant within the lumen and then advances the collapsed implant from the delivery tool, through the trocar cannula and into the abdominal cavity. A cartridge holds the prosthesis in its normal expanded configuration until the surgeon is ready to implant the device.

It is among the general objects of the invention to provide a mesh implant which is suitable for laparoscopic herniorrhaphy.

It is a further object of the invention to provide a mesh implant for repairing direct and indirect inguinal hernias.

It is a further object of the invention to provide a mesh implant which reduces the incidence of postoperative adhesions.

An additional object of the invention is to provide an instrument for loading and delivering the mesh implant at the surgical site.

Other objects and features of the present invention will become apparent from the following detailed description when taken in connection with the accompanying drawings which disclose multiple embodiments of the invention. It is to be understood that the drawings are designed for the purpose of illustration only and are not intended as a definition of the limits of the invention.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following drawings in which:

FIG. **1** is an illustration of prior art mesh logs or plugs used to repair direct and indirect inguinal hernias;

FIG. **2**(*a*) is an illustration of the implant in accordance with the present invention;

FIG. **2**(*b*) is an illustration of a preperitoneal repair using the mesh implant shown in FIG. **2**(*a*);

FIGS. **3**(*a*)–(*i*) are illustrations of variously shaped anti-migration barbs for preventing movement of the implant;

FIG. **4**(*a*) is an illustration of an adhesion resistant implant according to the present invention;

FIG. **4**(*b*) is an illustration of an intraperitoneal repair using the implant shown in FIG. **4**(*a*);

FIGS. **5**(*a*)–(*b*) are illustrations of the loading and delivery tool in accordance with the present invention;

FIG. **6** is an illustration of a loading and delivery tool in accordance with the present invention with an arrangement for arresting axial movement of the shaft; and

FIGS. **7**(*a*)–(*c*) are schematic representations of a method of loading and delivering a mesh implant to repair an inguinal hernia.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The implantable prosthesis **10** for repairing and reinforcing a ruptured or defective muscular wall illustrated in FIGS. **2**(*a*)–**2**(*b*) includes a pliable tissue infiltratable fabric **12** and a semi-rigid frame **14**. The fabric includes a plurality of openings which allow sufficient tissue ingrowth to secure the prosthesis to healthy tissue surrounding the defect site. The frame or skeleton is more rigid than the fabric and maintains the prosthesis in a predetermined shape, improving the handleability of the mesh implant at the surgical site. The frame also may provide the implant with a sufficient hoop strength to prevent the mesh fabric from collapsing into the defect. In the repair of inguinal hernias, the semi-rigid frame seats against the sound abdominal tissue **16** surrounding the defect **17**, the tissue infiltratable fabric extending across the opening of the hernia without filling the void. In the preperitoneal procedure illustrated, the implant **10** is anchored under the peritoneum **18**.

The relatively flat implant is sufficiently pliable to allow the surgeon to roll the implant into a narrow cylinder which is suitable for loading into the lumen of a trocar cannula. Upon deployment, the implant reverts back to its normal flat configuration. Alternatively, the unstressed implant may be formed with a slight convexity or concavity. The shape and size of the prosthesis, and of the respective fabric and frame, may vary according to the surgical application as would be apparent to those of skill in the art.

The tissue infiltratable fabric **12** includes a plurality of interstices or pores which are of sufficient size and orientation to allow tissue ingrowth. The frame has a predetermined shape and size sufficient to support the mesh relative to the herniated site, the frame sitting on the sound tissue surrounding the defect and the body portion of fabric extending completely across the opening of the defect. Preferably, the frame is ring-shaped, providing the implant with an inherent hoop strength which prevents the mesh from deflecting into the defect opening. The ring-shaped frame may be circular or elliptical, although alternative designs would include any shape which defines a boundary surrounding the opening of the hernia. For example, a square, diamond or hourglass configuration would be suitable so long as the ring surrounds the weakened area. The ring may be formed from a single element or, alternatively, from a series of spaced elements which together form a semi-rigid boundary about the body portion of the mesh fabric. Preferably, the ring has a rectangular cross-section, although other cross-sectional shapes would be suitable as would be apparent to those of skill in the art.

The rigidity of the ring relative to the mesh fabric stiffens the implant, improving handleability particularly when awkward surgical tools are being used to manipulate the implant. Thus, non-ring shaped frames, such as a criss-crossed arms configuration, would provide the necessary stiffness although such frames would lack the favorable hoop strength property of the circular or oval shaped frames.

The frame **14** is preferably attached to the fabric by insert molding. The mesh fabric may be surface treated with a carbon dioxide plasma etch prior to molding which may enhance the union of the mesh and the ring when formed from dissimilar materials. Alternatively, the ring and mesh may be ultrasonically welded, heat sealed or adhesively bonded. The frame may be overlayed onto a surface of the mesh fabric or may be joined to the fabric edges.

The fabric **12** preferably is formed of a sheet of knitted polypropylene monofilament mesh fabric such as MARLEX mesh available from C.R. Bard, Inc. When implanted, the polypropylene mesh stimulates an inflammatory reaction which promotes rapid tissue ingrowth into and around the mesh structure. Alternatively, other surgical materials which are suitable for tissue reinforcement and/or defect closure may be utilized including PROLENE, MERSELENE, DACRON, TEFLON textile based meshes, microporous polypropylene sheeting (CELGARD), and expanded PTFE (GORETEX). Absorbable meshes, including polyglactin (VICRYL) and polyglycolic acid (DEXON), may be suitable for applications involving temporary repair of fascial defects. It also is contemplated that the mesh fabric may be formed from monofilament or multifilament yarns and that woven, molded and other recognized methods of forming prosthetic mesh materials would be suitable.

Non-tissue infiltratable fabrics also may be supported by the ring-shaped frame. Silicone elastomer sheeting, such as SILASTIC Rx Medical Grade Sheeting (Platinum Cured) distributed by Dow Corning Corporation, would be suitable. The silicone elastomer sheeting may be reinforced with DACRON or other reinforcing materials. It is contemplated that oxidized, regenerated cellulose (Intercede(TC7)) also may have applications in the present invention.

The ring **14** may be formed from a polypropylene material or a silicone material. Other semi-rigid materials which are stiffer than the mesh fabric yet sufficiently pliable to be rolled-up in the delivery lumen also may be suitable. Alternatively, the ring may be formed by hot or cold forming a ring-shaped depression in the mesh sheet. The formed pattern is more rigid than the nonformed body portion of the mesh, providing a stiffer implant with improved handleabil-

ity. Building up the edges of the body portion with additional mesh material, for example, by superposing rings of mesh around the body portion or heat setting folds of mesh from outlying portions of the fabric, also would increase the dimensional stability of the implant.

The implant **10** may include spaced barbs **22** for preventing migration of the implant until tissue infiltration securely anchors the mesh relative to the rupture site. The barbs grab, pierce or otherwise anchor to the tissue and include a variety of shapes as shown in FIGS. **3**(*a*)–(*i*). The barbs **22** may extend perpendicularly from the implant. As illustrated, the barbs may have a semi-circular cross-sectional shape, a triangular cross-sectional shape, or a pointed distal tip. The barbs preferably are uniformly spaced about the ring and may be integrally molded with the ring.

In a representative embodiment, the implant includes a 2.125 inch diameter circular piece of die-cut MARLEX mesh knit from MARLEX polypropylene monofilament with a 0.006 inch diameter. A 0.030 inch thick and 0.28 inch wide circular polypropylene ring having a 2.125 inch outer diameter and a 1.980 inch inner diameter is insert molded to the MARLEX sheet.

An implant **30** particularly suited for intraperitoneal procedures is illustrated in FIGS. **4**(*a*)–(*b*) and includes a semi-rigid ring **32**, a mesh fabric **34** formed of a material which stimulates an inflammatory reaction in tissue after implantation and an adhesion barrier **36** which isolates the mesh fabric **34** from sensitive tissues and organs. In an intraperitoneal procedure, the peritoneum **35** is located under the implant and therefore is not available to provide a biological barrier between the implant and the intestine. The barrier layer **36** separates the prosthetic mesh **34** from the abdominal viscera, preventing intestinal adhesion and fistulization which may result from an inflammatory reaction of the bowel and the mesh. A suitable barrier material would be a silicone elastomer, such as SILASTIC, which does not substantially stimulate adhesion formation when implanted in tissue and is significantly less likely to cause an inflammatory reaction with neighboring tissue than would a prosthetic mesh.

The portions of the MARLEX mesh fabric extending outside the ring form ears or anchoring projections **38** through which staples **40** may be driven to secure the implant to the fascia. Stapling of the ears serves the same function as the antimigration barbs, provisional anchoring of the implant until fill tissue invasion of the prosthetic mesh. The barrier layer **36** and prosthetic mesh are bonded or sewn to the ring **32**. The edges **41** of the barrier outside of the ring which are not directly connected to the underlying mesh or the ring, may be lifted to allow stapling of the anchoring portions **38** to the peritoneum, provisionally anchoring the implant until sufficient tissue ingrowth holds the prosthesis in place. Upon release, the barrier margin **41** falls back over the staple and anchoring portions, providing a non-scarifying barrier between the implant and the bowel. In an alternative arrangement, the barrier and mesh may be directly attached with the ring formed along either of the mesh or barrier surfaces.

The mesh implants are too large to be inserted through the lumen of a trocar cannula. An instrument **200** for loading the implant into a narrower configuration and then delivering the implant through the trocar cannula and into the abdominal cavity is illustrated in FIGS. **5**(*a*)–(*b*). By loading the implant at the surgical site, rather than providing the implant in a pre-rolled configuration within the instrument **200**, a permanent setting or deformation of the implant is avoided. Such a kinked implant may not seat flush with the abdominal wall and might provide localized areas of weakness which could lead to recurrent herniation.

The loading and delivery instrument **200** includes a main body **202** having a lumen **204** for receiving and collapsing the implant **205** into a slender rolled configuration which is advanceable through the lumen of the trocar cannula. An elongated introducer shaft **206** is rotated, by turning a knurled knob **203**, which winds the implant in the lumen into a narrow cylindrical configuration. After the implant is reduced in size, the stepped distal end **207** of the main body is inserted into the proximal end of the previously placed trocar cannula. The proximal end **209** of the elongated shaft (outside of the trocar cannula) is manipulated to advance the implant from the main body, through the trocar cannula and into the abdominal cavity. No longer confined by the lumen walls of the main body and the trocar cannula, the implant unfurls into its relaxed flat configuration. Rotating the shaft **206** in the direction opposite the one used in winding should facilitate deployment of the implant. Instruments inserted through additional trocar cannulae may then be manipulated by the surgeon to position the implant about the herniated area.

The main body **202** includes a uniform diameter central lumen **204** which is sized to reduce the implant to a predetermined diameter compatible with the trocar cannula lumen. A cartridge **210** extends from the main body and includes a sidewall **252**, and a base **249** on which the implant, in the expanded form, is seated in readiness for loading and delivery. The cartridge **210** may be formed integral with the main body or may be removably connected thereto. A door **220** in the top **250** of the cartridge may be provided for access to the implant, for example, to check the integrity of the implant. Tabs **211** on the cartridge floor align the full-sized implant with an opening **212** in the main body.

The edge of the implant is threaded to a slot **213** at the distal end of the shaft which may be tapered to facilitate reception of the edge of the implant. A projection may be provided at the base of the slot **213** to pinch or grasp the implant, securing the implant and shaft during initial rotation. A pin extends from the knob **203** into a longitudinal groove in shaft **206**, imparting rotational movement to the shaft as the knob is turned. An enlarged bulbous tip stabilizes the distal end of the shaft relative to the main body. A cap at the proximal end of the shaft serves as a mechanical stop of forward axial movement.

Premature axial movement of the introducer shaft may produce a helically wound implant which is too large to travel through the main body or the trocar cannula. An arrangement for arresting axial movement during rotation of the shaft is illustrated in FIG. **6**. External control threads **230** in the shaft **206** are engaged to internal threads **232** in the main body **202**, limiting forward movement as the implant is wound about the shaft. The number, shape and angle of the threads would vary depending upon the number of rotations of the shaft necessary to completely wind the implant.

The loading and delivery of the implantable prosthesis is shown in FIGS. **7**(*a*)–(*c*). While the operation of the invention is discussed in connection with the repair of an indirect inguinal hernia, a similar loading and delivery procedure would be followed for the repair of a direct inguinal hernia and other muscle wall defects. A laparoinflator is inserted through a small puncture in the abdomen near the navel. Carbon dioxide or other insufflating gas is introduced under pressure until the abdominal cavity is sufficiently inflated to allow the surgical tools to be manipulated relative to the

hernia site. A sharp point of a trocar is used to form an opening through the distended abdominal wall. The trocar is withdrawn, leaving a hollow trocar cannula **300** in the newly formed passageway. A 45° laparoscope is inserted through the cannula and is connected to a television monitor which allows the surgeon to view the interior of the abdominal cavity and to assess the location, type and size of the defect. Additional cannulae are inserted through bilateral punctures in the abdominal wall. Graspers and electrocautery tools are manipulated through these cannulae to dissect the hernia sac, if indicated, and to prepare the hernia site for the implant.

A loading and delivery tool **302** carrying a suitably sized implant is removed from its sterilized packaging. The reduced diameter distal end is inserted into one of the previously emplaced trocar cannula. Rotation of the shaft draws the expanded flat implant from the cartridge into the main body lumen where it becomes wrapped around the shaft surface. The collapsed implant is guided towards the abdominal cavity by advancing the proximal end of the elongated shaft. The implant reverts to its expanded configuration upon exiting the trocar cannula. Instruments are manipulated by the surgeon to position the ring of the implant around the opening of the defect. A grasper or other tool may be used to press the ring against the muscle, securing the antimigration barbs to the healthy tissue surrounding the rupture. The inherent hoop strength of the implant prevents the mesh portion from collapsing into the void. Tissue growth through the mesh fabric extending across the opening is rapid, particularly when the mesh is formed of a material which stimulates an inflammatory reaction with tissue. In a matter of days, if not hours, tissue infiltration of the mesh secures the implant in place, repairing the herniated defect.

The present invention therefore provides an implantable prosthesis and a method and device for loading and delivering the prosthesis, amongst which are certain of the following advantages. The mesh implants provide an effective means for repairing an indirect or direct inguinal hernia by occluding the opening of the defect without requiring that the entire void be filled. The pliable prosthesis is rollable into a configuration which is small enough to be inserted through a laparoscopic cannula, yet is sufficiently resilient to revert to the normal expanded configuration which is required to evenly cover the herniated site. The increased dimensional stability of the implant enhances handleability of the mesh fabric during laparoscopic surgery. The delivery tool provides a simple and quick system for loading and delivering the implant to the abdominal cavity at the surgical site.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other equivalents, embodiments and modifications of the invention may be apparent to those skilled in the art.

What is claimed is:

1. An implantable prosthesis for occluding the opening of a muscle or tissue defect, comprising:

a flexible, generally flat patch of implantable material including a body portion constructed and arranged to cover the defect opening when positioned thereagainst; and

a plurality of barbs disposed on said patch of implantable material and extending at spaced locations from said patch of implantable material, wherein said plurality of spaced barbs prevent migration of said implantable prosthesis after implantation.

2. The implantable prosthesis recited in claim **1**, wherein said patch of implantable material includes a mesh fabric having a plurality of interstices constructed and arranged to allow tissue ingrowth so that the mesh becomes secured to neighboring tissue.

3. The implantable prosthesis recited in claim **1**, wherein said plurality of spaced barbs extend perpendicularly from said patch of implantable material.

4. The implantable prosthesis recited in claim **1**, wherein said plurality of spaced barbs have a semi-circular cross-sectional shape.

5. The implantable prosthesis recited in claim **1**, wherein said plurality of spaced barbs have a triangular cross-sectional shape.

6. The implantable prosthesis recited in claim **1**, wherein said plurality of spaced barbs have a pointed distal tip.

7. The implantable prosthesis recited in claim **1**, wherein said plurality of spaced barbs are uniformly spaced about said patch of implantable material.

8. The implantable prosthesis recited in claim **1**, wherein said patch further includes an implantable base attached to and circumscribing said body portion, said implantable base being constructed and arranged to urge said body portion toward a generally flat configuration.

9. An implantable prosthesis for occluding the opening of a muscle or tissue defect, comprising:

an implantable material including a body portion constructed and arranged to cover the defect opening when positioned thereagainst;

an implantable base attached to and circumscribing said body portion, said implantable base being constructed and arranged to urge said body portion toward a non-tubular configuration; and

a plurality of barbs disposed at spaced locations on said implantable base and extending from said implantable base, wherein said plurality of spaced barbs prevent migration of said implantable prosthesis after implantation.

10. The implantable prosthesis recited in claim **9**, wherein said plurality of spaced barbs are integrally formed with said implantable base.

11. The implantable prosthesis recited in claim **9**, wherein said plurality of spaced barbs are uniformly spaced about said implantable base.

12. The implantable prosthesis recited in claim **9**, wherein said plurality of spaced barbs extend perpendicularly from said implantable base.

13. An implantable prosthesis for occluding the opening of a muscle or tissue defect, comprising:

a flexible, generally flat patch of implantable material including a body portion constructed and arranged to cover the defect opening when positioned thereagainst; and

a plurality of anchors disposed on said patch of implantable material and extending at spaced locations from said patch of implantable material, wherein said plurality of spaced anchors prevent migration of said implantable prosthesis after implantation.

14. The imnlantable prosthesis recited in claim **13**, wherein said patch of implantable material includes a mesh fabric having a plurality of interstices constructed and arranged to allow tissue ingrowth so that the mesh becomes secured to neighboring tissue.

15. The implantable prosthesis recited in claim **13**, wherein said plurality of spaced anchors extend perpendicularly from said patch of implantable material.

16. The implantable prosthesis recited in claim 13, wherein said plurality of spaced anchors have a semi-circular cross-sectional shape.

17. The implantable prosthesis recited in claim 13, wherein said plurality of spaced anchors have a triangular cross-sectional shape.

18. The implantable prosthesis recited in claim 13, wherein said plurality of spaced anchors have a pointed distal tip.

19. The implantable prosthesis recited in claim 13, wherein said plurality of spaced anchors are uniformly spaced about said implantable material.

20. The implantable prosthesis recited in claim 13, wherein said patch further includes an implantable base attached to and circumscribing said body portion, said implantable base being constructed and arranged to urge said body portion toward a generally flat configuration.

21. An implantable prosthesis for occluding the opening of a muscle or tissue defect, comprising:

an implantable material including a body portion constructed and arranged to cover the defect opening when positioned thereagainst;

an implantable base attached to and circumscribing said body portion, said implantable base being constructed and arranged to urge said body portion toward a non-tubular configuration; and

a plurality of anchors disposed at spaced locations on said implantable base and extending from said implantable base, wherein said plurality of spaced anchors prevent migration of said implantable prosthesis after implantation.

22. The implantable prosthesis recited in claim 21, wherein said plurality of spaced anchors are integrally formed with said implantable base.

23. The implantable prosthesis recited in claim 21, wherein said plurality of spaced anchors are uniformly spaced about said implantable base.

24. The implantable prosthesis recited in claim 21, wherein said plurality of spaced anchors extend perpendicularly from said implantable base.

25. An implantable prosthesis for occluding the opening of a muscle or tissue defect, comprising:

a flexible, generally flat patch of implantable material including a body portion constructed and arranged to cover the defect opening when positioned thereagainst; and

means, disposed on said patch of implantable material, for preventing migration of said implantable prosthesis after implantation.

26. The implantable prosthesis recited in claim 25, wherein said patch of implantable material includes a mesh fabric having a plurality of interstices constructed and arranged to allow tissue ingrowth so that the mesh becomes secured to neighboring tissue.

27. The implantable prosthesis recited in claim 25, wherein said patch further includes means for maintaining said body portion in a predetermined shape.

28. The implantable prosthesis recited in claim 27, wherein said means for preventing migration is disposed on said means for maintaining said body portion in the predetermined shape.

29. The implantable prosthesis recited in claim 1, consisting essentially of said patch and said plurality of spaced barbs.

30. The implantable prosthesis recited in claim 1, wherein said patch is sufficiently flexible to be rolled into a cylindrical shape.

31. The implantable prosthesis recited in claim 9, wherein said implantable base is constructed and arranged to urge said body portion toward a generally flat configuration.

32. The implantable prosthesis recited in claim 13, consisting essentially of said patch and said plurality of spaced anchors.

33. The implantable prosthesis recited in claim 13, wherein said patch is sufficiently flexible to be rolled into a cylindrical shape.

34. The implantable prosthesis recited in claim 21, wherein said implantable base is constructed and arranged to urge said body portion toward a generally flat configuration.

35. The implantable prosthesis recited in claim 25, consisting essentially of said patch and said means for preventing migration.

36. The implantable prosthesis recited in claim 25, wherein said patch is sufficiently flexible to be rolled into a cylindrical shape.

37. An implantable prosthesis for occluding the opening of a muscle or tissue defect, comprising:

an implantable material including a body portion constructed and arranged to cover the defect opening when positioned thereagainst;

means for urging said body portion toward a non-tubular configuration; and

means, disposed on said means for urging, for preventing migration of said implantable prosthesis after implantation.

38. The implantable prosthesis recited in claim 37, wherein said implantable material includes a mesh fabric having a plurality of interstices constructed and arranged to allow tissue ingrowth so that said mesh fabric becomes secured to neighboring tissue.

39. The implantable prosthesis recited in claim 37, wherein said implantable material includes a flexible, generally flat patch including said body portion, said means for urging being attached to said patch and circumscribing said body portion.

40. The implantable prosthesis recited in claim 37, wherein said means for urging includes means for urging said body portion toward a generally flat configuration.

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